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Dated 3 July 2003

Andrew Jersey



13 JUN 2002

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Request for grant of a patent

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13 JUN 2002
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P867/74/GBR
13 JUN 2002 072557A-1 0033452. Patent application number
(The Patent Office will fill in this part)

0213584.6

/7700 0.00-0213584.6

3. Full name, address and postcode of the or of each applicant (underline all surnames)

N.K. MOHINDRA
18 Wimpole Street
LondonW1M 7AD
ENGLAND

Patents ADP number (if you know it)

8401960001

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

Appliance for reducing facial aging

5. Name of your agent (if you have one)

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)

CASTLES
1 King Street
Bakewell
Derbyshire
DE45 1DZ

7336522002

Patents ADP number (if you know it)

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number

Country Priority application number
(if you know it) Date of filing
(day / month / year)

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application Date of filing
(day / month / year)8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if
a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
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Continuation sheets of this form

Description

5

Claim(s)

Abstract

Drawing(s)

10. If you are also filing any of the following, state how many against each item.

Priority documents

Translations of priority documents

Statement of inventorship and right to grant of a patent (Patents Form 7/77)

Request for preliminary examination and search (Patents Form 9/77)

Request for substantive examination
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Any other documents
(please specify)

11.

I/We request the grant of a patent on the basis of this application.

Signature

G.J. Buckley

Date

CASTLES

13th June 2002

G.J. BUCKLEY 01629 813505

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Patents Form 1/77

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APPARATUS FOR REDUCING FACIAL AGING

The invention is an appliance designed to be worn in the mouth, with the aim of improving and delaying the signs of facial ageing.

Background to the invention

The basic appliance is called a pivot appliance and has been used in dentistry since the 1930s. Its original purpose was to separate the jaws so that the inclines of the teeth would not dictate how the jaws meet. This would allow the bite of the patient to be corrected. This appliance would allow the facial muscles to relax, resulting in the jaw and the condyle in the temporo mandibular joint resting in an unrestrained position. This would result in relief of pain associated with the temporo mandibular joint (tmj) syndrome.

This appliance is made thus:

A plaster mould is made of the patient's mouth by taking an impression of the lower teeth with any dental reversible or irreversible impression material. From this impression, a mould is made in plaster, which is an exact duplicate of the patient's lower jaw. This mould is then used to make an acrylic appliance with wire clips to fit in the patient's mouth. This appliance is then modified to increase the height of the acrylic on top of the teeth. This is done by using a swallowing technique (command swallow) which establishes the correct height of the appliance for the patient. The patient would wear this appliance under the direction and supervision of his dentist until relief of pain is achieved. Some dentists would advocate that the bite of the patient has to be permanently altered to achieve permanent relief. This would involve orthodontic treatment to change the position of the teeth, or it could be done by crowding the teeth. No one advocated that the position dictated by the swallowing method (command swallow), should be used to restore the patient's new bite permanently.

Dr. Nick Mohindra, a dental surgeon working in general practice developed an interest around 1990, in patients who presented with facial pain symptoms, i.e. tmj syndrome, and used this pivot appliance to treat them. He believed that these patients would benefit from being permanently restored to the new biting position dictated by the command swallow position. Until then the traditional thinking in dentistry was that one should not alter the way one's teeth meet. Therefore Dr. Mohindra's views were challenging those in mainstream dentistry. He found he could increase vertical dimension i.e. the way teeth meet together, by up to 20mm, a height hitherto not believed possible. The results of his findings were published in the British Dental Journal in an iconoclastic paper in 1996, entitled "A preliminary report on determining the vertical height of occlusion by the position of the

mandible in the swallowing technique." Most of his work was done on edentulous patients, because it was easier to alter their vertical dimension, by providing them with new dentures at the new height. While carefully monitoring these patients and mindful of the need of scientific proof that would be paramount to gain acceptability for this technique, Dr. Mohindra started taking photographs of these patients as part of the monitoring process. The photographs resulted in the observation that the patients' facial aesthetics dramatically improved as a result of this technique. Dr. Mohindra extended his technique to partly dentate patients and ultimately to fully dentate patients. He left his general practice to set up Added Dimension Dentistry in central London to allow him to treat patients who wanted this work done, and to carry out further research. His second paper was published this year in the British Dental Journal entitled "The effect of increasing vertical dimension on facial aesthetics". The findings of this paper were that 80% of the patients treated, thought they looked between 5 and 20 years younger. These views were backed up by an independent panel who studied the before and after photographs and reached the same conclusions. When asked which facial features had improved, 90% said lips, 70% said jawline, 40% said cheeks, 30% said eyes and 30% said skin. These results show that what is done in the mouth has much wider impact than is traditionally thought.

Dr. Mohindra's observations led him to believe that similar results could be obtained without permanently increasing the vertical dimension of occlusion, if the patients were to have their vertical dimension increased for a short period with a removable appliance. He calls this appliance the Rejuvenator (this appliance has been trademarked as the "ADD Facial Rejuvenator"). It is based on the original pivot appliance and is made in exactly the same way, and the height for each patient is determined individually by the swallowing method. Dr. Mohindra's observations regarding the use of this appliance lead him to believe that the following results can be achieved:

- 1) increased collagen production by the fibroblasts
- 2) muscles will hypertrophy
- 3) changes in the fibre composition of the muscles
- 4) prevent apoptosis
- 5) increased blood flow to facial muscles, skin, and facial features
- 6) reversal of sun damage to the facial skin
- 7) improvement in eyesight
- 8) improvement in hair quality
- 9) fuller lips
- 10) uplifting of the ptotic cheeks
- 11) improvement in nose and chin droop
- 12) reduction of jowels
- 13) reduction of wrinkles
- 14) improvement in skin colour (skin darkens with ageing)

- 15) improvement in micro vascularity to the skin
- 16) reduction in the loose skin above and below the eyes
- 17) strengthening and remodelling of the facial and neck bones
- 18) improvement in cases of acne
- 19) improvement in skin in cases of Bell's Palsy
- 20) improvement in skin of patients who have had skin cancer

These results show the Rejuvenator to be a device which will truly improve and delay the signs of facial ageing.

Up until now, the appliance has been individually designed and made for the patient. It can be made out of various metals, plastic and metal. The plastic can be acrylic or thermoplastic. The metal can be chrome cobalt or gold. The appliance has to be made by a trained and approved dental technician. It is regarded as a medical device and therefore has to meet the Medical Devices Agency standards.

The object of the present invention is to provide an appliance for reducing facial aging that can be mass produced on an industrial basis, thereby obviating the hitherto necessity for customized manufacture in a laboratory of an appliance that has been individually designed and made for a particular patient.

In accordance with the present invention there is provided an universal appliance for reducing facial aging.

The universal appliance is of similar design to the Rejuvenator, except that it is adapted to provide a predetermined vertical separation of the jaws. It is also not permanent and will have to be replaced after 1-2 years. No laboratory processes are involved in fitting this appliance.

The universal appliance is employed to improve the signs of facial aging and no other device has been used specifically for this application. The universal appliance does not have to be made individually for a patient, unlike the Rejuvenator, but the same appliance can be adapted for an individual. Occlusal appliances have been used for a long time for various reasons, mostly to reduce the symptoms of TMD (Temporo Mandibular Disorder). The universal appliance uses a height for occlusal separation which is predetermined. Though the height is predetermined, it can be adjusted for individual patients. The appliance is used for eating which makes it different from any other appliance. Use of the universal appliance is preferably limited to a 6 week period at a time with a 4 month interval in between uses. No other appliance has been used on this basis.

The appliance is going to be developed in to a universal appliance, which can be modified for use by the individual. It will be manufactured by an approved factory. It will be possible for it to be fitted by any doctor e.g. plastic surgeon, dermatologist or by a dentist. This universal appliance will be made from soft and hard plastics, the base being thermoplastic. The height of the hard acrylic would be pre determined at between 3 and 15 mm. The biting surface will be hard and cover the back teeth i.e. the molars and premolars, and this will be made of hard acrylic, and attached to this will be the soft thermoplastic base which will fit over the teeth. The appliance would be placed in hot water to soften it, and then fitted over the lower teeth. To achieve an accurate fit, a denture lining material will be supplied to enable the operator to get the best fit. This will be placed on the fitting surface of the appliance and allowed to set in the mouth. The patient will be given an instruction sheet along with a suggested use regime. It is recommended that the patient returns to see their doctor/dentist to monitor progress.

Measurable Improvements.

To date the improvements achieved as a result of wearing the rejuvenator have merely been those observed by taking before and after photographs of the patients. However, trends have been observed by studying these photographs.

Based on questionnaires sent to the patients, 90% of whom said that they believed they had seen an improvement in their lips; 80% an improvement in their skin and about the same number an improvement in their jawline. These were the areas where most patients felt there had been an improvement, but the other features where improvement was noticed were: the skin above the upper eyelid becoming tighter, size of the eyes becoming larger, bags underneath the eyes improving, crows feet improving, cheeks lifting up, shape of nose improving, neck improving.

Enlarged photographs of the skin underneath the eyes and the cheeks shows smoothening of the roughness caused by sun damage and that the dark patches also caused by this, lighten. Pores of the skin that have opened up also start to close. The depth of the wrinkles on the face also reduces. Changes in the skin could perhaps also be measured by ultrasound to show the thickness of the various layers of the skin. We would have to talk to a dermatologist to ascertain more about this.

The above improvements are those which can actually be seen. The improved blood flow to the facial features could be measured by thermal imaging of the face. This is quite a new technology and I would need to do further research to find out if this could be a measuring tool. From what I have read, it is believed that thermal imaging could be as accurate as finger printing. The other way to measure increased vascularity would be to use laser doppler studies to check if there is increased blood flow to features like the eyes. Again, we need more expert input on this, but perhaps this is a tool which would be possible to use in the surgery.

C.T. scans and MRI scans would show the increase in the thickness of the muscles and any change in density and would be useful for trials, but ethical approval and costs could be a drawback.

Skin biopsies taken in the cheek area or at the side of the eyes, when viewed with electron microscopy and ——microscopy would show the improvement in sun

damage and improvement in micro vascularity, and increase in thickness due to increased collagen.

Cell Biology:

Fluid taken from the muscles would show that certain growth factors (one being MGF), will start to be produced when the rejuvenator is being worn.

In conclusion, users of the universal appliance may experience

- Reduced lines around the mouth, eyes & generally around the whole face
- Reduced bags under the eyes
- Tightened and strengthened facial muscles
- Increased blood flow to the skin making it more radiant, healthy and smoother
- Increased fullness of the lips
- Strengthening and firming of the jaw line.

Other benefits reported by patients include improvements in:

- head, neck and shoulder pains
- range of movement of neck and shoulder joints
- eyesight
- hair quality
- joint mobility of the whole body

Head and neck ache sufferers have also reported an improvement in their symptoms with the facial rejuvenator.

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